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|-----------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/040,815      | 01/07/2002  | Leonard Harrison     | 10308B              | 4822             |

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SCULLY, SCOTT, MURPHY & PRESSER  
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Garden City, NY 11530

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| EXAMINER         |  |
| EWOLDT, GERALD R |  |

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| ART UNIT | PAPER NUMBER |
| 1644     |              |

|            |               |
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| MAIL DATE  | DELIVERY MODE |
| 11/19/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/040,815   | <b>Applicant(s)</b><br>HARRISON ET AL. |  |
|                              | <b>Examiner</b><br>G. R. Ewoldt, Ph.D. | <b>Art Unit</b><br>1644                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1644

### DETAILED ACTION

1. Applicant's amendment and remarks filed 9/11/07 are acknowledged.
2. Claims 16-18 are pending and are being acted upon.
3. Applicant has claimed the benefit of priority of U.S. Application No. 08/663,272 of which the instant application is a divisional application. Said benefit of priority is denied. The '272 application does not disclose a peptide comprising SEQ ID NO:1, i.e., a peptide of any length that includes the FFYTPKTRREAED sequence. The priority date of the instant application is now its filing date of 01/07/02.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 16-18 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,509,165.

As set forth previously, The '165 patent teaches a method of contacting T cells isolated from blood with SEQ ID NO:1 (SEQ ID NO:4 in the reference) and measuring T cell reactivity employing a proliferation assay (see particularly Column 5 line 15 - Column 16, line 32). NOTE, previous typographical error, column 16 was column 4.

Applicant's arguments, filed 9/11/07, have been fully considered but they are not persuasive. Applicant argues that "the '165 patent does not teach a method of contacting T cells

Art Unit: 1644

with a peptide having a sequence identical with instant SEQ ID NO: 1. It is observed that SEQ ID NO: 4 of the '165 patent is longer than instant SEQ ID NO: 1".

SEQ ID NO:4 of the '165 patent comprises SEQ ID NO:1 of the instant application and claims.

Applicant argues that the parent application of the '165 patent, U.S. Patent Application No. 08/272,229, does not teach the claimed method.

Given the new priority date of the instant claims the teachings of the parent application of the '165 patent are no longer relevant as the '165 patent's own filing date is sufficient.

6. The following are new grounds for rejection necessitated by Applicant's amendment.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter written description rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, a method employing a peptide comprising FFYTPKTRREAED (SEQ ID NO:1).

Applicant cites page 3, lines 12-28 of the instant specification in support.

Art Unit: 1644

The cite does not teach a peptide comprising FFYTPKTRREAED (SEQ ID NO:1), i.e., a peptide of any length that includes the FFYTPKTRREAED sequence.

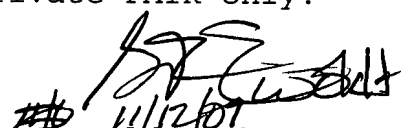
9. No claim is allowed.

10. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

  
G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600